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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,693	11/25/2003	William F. Kaemmerer	48169.00016/P0011089.00	3964

80788 7590 03/13/2009

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EXAMINER	
WOLLENBERGER, LOUIS V	
ART UNIT	**PAPER NUMBER**
1635	

MAIL DATE	DELIVERY MODE
03/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/721,693	KAEMMERER, WILLIAM F.	
	Examiner	Art Unit	
	Louis Wollenberger	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10,14,24,25,86,87 and 89-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10,14,24,25,86,87 and 89-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

Applicant's response filed 12/10/2008 has been considered. Rejections and/or objections not reiterated from the previous Office Action mailed on 8/13/2008 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Applicant's amendment to the claims, filed 12/10/2008, is acknowledged. With entry of the amendment, Claims 1, 10, 14, 24, 25, 86, 87, and 89-98 are pending and examined herein.

Specification/Drawings/Amendments

Applicant's amendment to pages 8, 9, and 28-30, filed 12/10/2008, removing references to Fig. 7 and deleting matter previously introduced into pages 28-30, are acknowledged. Applicant further requests deletion of Fig. 7 from the application. The amendments have been entered into the application. With entry of these amendments, previous objections to the specification under 35 U.S.C. 132(a) are hereby withdrawn.

To be clear, the only amendments to the specification which remain in the specification are 1) the amendment filed 11/6/2006, amending the cross-reference to related applications section of page 1 of the specification, and 2) the amendment to pages 8, 9, and 28-30, filed 12/10/2008, restoring the disclosure to its original text.

***

Applicant's attention is further directed page 31. There appears to be a typo at page 31, wherein the disclosure refers to an siRNA comprising SEQ ID NO:4 and 6. Reference to the

original sequence listing shows the sequence referred to as SEQ ID NO:4 at page 31 may be SEQ ID NO:5.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 10, 14, 24, 25, 86, 87, and 89-98 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the claims remain rejected as indefinite because of the recitation "a mapping means for locating a predetermined location in the brain," which appears in Part b of independent claims 1 and 90. Claim 90 more specifically reads "a mapping means for stereotactically locating a predetermined location in the brain of a patient."

The limitation "mapping means for locating (or stereotactically locating) a predetermined location in the brain" is being treated under 35 U.S.C. 112, sixth paragraph (see MPEP 2181).

35 USC 112, sixth paragraph, states that "An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof."

In the instant case, the specification neither expressly nor inherently links or associates the means-plus-function limitation "a patient-specific intraoperative mapping means for locating a predetermined location in the brain" with any specific structure or equivalent thereof.

35 USC §112, sixth paragraph, requires some disclosure of structure in the specification corresponding to the claimed means.

> "[W]hile it is true that the patentee need not disclose details of structures well known in the art, the specification must nonetheless disclose some structure." Default Proof, 412 F.3d at 1302; see also Atmel, 198 F.3d at 1382 ("There must be structure in the specification" and the requirements of §112, ¶ 6 will not be met when there is "a total omission of structure."); Med. Instrumentation, 344 F.3d at 1211 ("If the specification is not clear as to the structure that the patentee intends to correspond to the claimed function, then the patentee has not paid [the price for use of the convenience of broad claiming afforded by §112, ¶ 6] but is rather attempting to claim in functional terms unbounded by any reference to structure in the specification. Such is impermissible under the statute."). "…a bare statement that known techniques or methods can be used does not disclose structure. To conclude otherwise would vitiate the language of the statute requiring "corresponding structure, material, or acts described in the specification." See *Biomedino LLC v. Waters Technologies Corp*., 83 USPQ2d 1118 (Fed. Cir. 2007).

Accordingly, the claims are considered to be indefinite because one skilled in the art would not be able to identify the structure, material or acts from description in the specification for performing the recited function (MPEP 2181). Therefore, the metes and bounds of the claim are unclear.

Response to Arguments

Applicant's arguments suggest Applicant considers the amendment to the claims, removing the words "patient specific intraoperative" to be remedial. However, the instant rejection is directed to deficiencies related to the 35 USC 112, sixth paragraph, means-plus-function limitation found in Part b of claims 1 and 90: "means for locating" and "means for stereotactically locating," respectively. The instant specification fails to identify any structure capable of performing this function. Applicant has pointed to the "Devices" section of the specification (page 28 and 29) as support. However, while this section describes, delivery devices, pumps, and catheters, which may be used with the invention, and cites references

describing such devices, this section does not define, describe, or mention any "mapping means" or structure related thereto.

While page 28 does provide support for a stereotactically implanted catheter, and while the specification provides support for using stereotactically implanted catheters in conjunction with pumps to deliver siRNA to specific locations in the brain, the specification does not enable one of skill to discern what structures or devices are to be used as "mapping means." As a result, one of skill would not know what systems are specifically included or excluded by the claims.

Claim Rejections - 35 USC § 112, first paragraph, (written description)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 10, 14, 24, 25, 86, 87, and 89-98 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Adequate written description support does not exist for the limitation "a patient-specific intraoperative mapping means for locating a predetermined location in the brain," recited in independent claims 1 and 90. (Dependent claims are rejected therefor.)

Adequate written description does not exist in the specification as filed for the structure(s) or equivalents thereof corresponding to the function now recited in the claims. In

fact, no structure or equivalent thereof is explicitly identified or described for performing the function now recited. Therefore, the specification as filed does not enable one of skill to immediately envision the structures that would peform the function. As an ancillary result, one of skill would not reasonably conclude from the specification as filed that the inventor was in possession of the structure(s) and all equivalents thereof that would perform the function as of the filing date.

MPEP 2181, Section II, states in part that

> "If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112." *In re Donaldson Co.*, 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc)."
> "Whether a claim reciting an element in means- (or step-) plus-function language fails to comply with 35 U.S.C. 112, second paragraph, because the specification does not disclose adequate structure (or material or acts) for performing the recited function is closely related to the question of whether the specification meets the description requirement in 35 U.S.C. 112, first paragraph. See *In re Noll*, 545 F.2d 141, 149, 191 USPQ 721."

As explained above in the rejection under 35 USC 112, second paragraph, the limitation is being interpreted as a means-plus-function limitation, according to 35 USC 112, sixth paragraph. As further explained above, the specification does not clearly link or associate the limitation with any particular structure or equivalent thereof.

A means- (or step-) plus-function claim limitation is adequately described under 35 U.S.C. 112, para. 1, if the written description adequately links or associates adequately described particular structure, material, or acts to the function recited in a means- (or step-) plus-function claim limitation. See *Biomedino LLC v. Waters Technologies Corp.*, 83 USPQ2d 1118 (Fed. Cir. 2007).

In the instant case this criterion has not been satisfied. A review of the instant application fails to find any description of a structure corresponding to a "mapping means for locating a predetermined location in the brain of patient."

While adequate written description exists for drug delivery devices comprising catheters, ports, and pumps, which may be surgically implanted using conventional stereotactic neurosurgical techniques described in the prior art, explicit written description support does not exist for the particular devices or elements that should be used as a "mapping means" for locating a predetermined location in the brain.

Accordingly, the instant claims are rejected for lack of written description.

Response to Arguments

Applicant argues one of skill would know that "imaging systems" available at the time of invention, from, for example, Medtronic, would be suitable as the means for the instantly recited function. However, no such evidence has been made of record. While the hypothetical person of skill in the art is charged with the knowledge of the prior art, it is unclear why one of skill would necessarily associate a specific "imaging system" from Medtronic with the limitation "mapping means for locating" and not any other device. The fact remains the instant specification fails to set forth an adequate disclosure showing what is meant by the means-plus-function language. While the disclosure of the structure (or material or acts) may be implicit or inherent in the specification if it would have been clear to those skilled in the art what structure (or material or acts) corresponds to the means (or step)-plus-function claim limitation, there is no evidence to show one of skill would necessarily know which structures correspond to the limitation (MPEP 2181).

Applicant cites and quotes selected passages from US Application 09/864,646, and states the passages provide support for suitable mapping means such as MRI, stereotactic technique, X-ray, and fluoroscopy. Application 09/864,646 is incorporated by reference at page 29. In complete context the specification states "Thus, the present invention includes the delivery of small interfering RNA vectors using an implantable pump and catheter, like that taught in U.S. Pat. Nos. 5,735,814 and 6,042,579, and further using a sensor as part of the infusion system to regulate the amount of small interfering RNA vectors delivered to the brain, like that taught in U.S. Pat. No. 5,814,014. Other devices and systems can be used in accordance with the method of the present invention, for example, the devices and systems disclosed in U.S. Ser. No. 09/872,698 (filed Jun. 1, 2001) and Ser. No. 09/864,646 (filed May 23, 2001), which are incorporated herein by reference."

"To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." Advanced Display Systems, Inc. v. Kent State Univ., 212 F.3d 1272, 54 USPQ2d 1673 (Fed. Cir. 2000).

While one of skill would reasonably look to 09/864,646 for information regarding devices and systems in general, the instant specification does not point to any particular passages or paragraphs therein, nor does it associate any particular paragraphs therein with structures that may be suitable for use as a "mapping means." Accordingly, whether one of skill would recognize any of the structures therein were structures contemplated by applicant to serve as mapping means in the context of the instant invention is unclear.

In the instant case, the instant specification does not point to any particular sections or passages in the incorporated document as material relevant to the "mapping means" language in the instant claims.

Claim Rejections - 35 USC § 112, first paragraph (New Matter)

Claims 1, 10, 14, 24, 25, 86, 87, and 89-98 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amendment to the claims submitted on 12/10/2008, introduces the limitations:

1. "said catheter comprising a radiographic marker" into claim 1;
2. "an intracranial access device comprising a radiographic marker" into claim 90;
3. "wherein said small interfering RNA hybridizes to a sequence identical to SEQ ID NO:1 within the ataxin-1 mRNA" into claim 1; and
4. "wherein said small interfering RNA comprises SEQ ID NO:2 and a sequence at least 90% complementary thereto" into claim 98.

MPEP 2163, Section II, Part A, states in part that there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed, *Wertheim*, 541 F.2d at 262, 191 USPQ at 96; however, with respect to newly added or amended claims, applicant should show support in the original disclosure for the new or amended claims.

With regard to #1 and #2, above, Applicant points to paragraphs 29-32 of US Application 09/864,646 for support. Application 09/864,646 is incorporated by reference at page 29 of the instant specification, which states "Other devices and systems can be used in accordance with the method of the present invention, for example, the devices and systems disclosed in U.S. Ser. No. 09/872,698 (filed Jun. 1, 2001) and Ser. No. 09/864,646 (filed May 23, 2001), which are incorporated herein by reference."

"To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." Advanced Display Systems, Inc. v. Kent State Univ., 212 F.3d 1272, 54 USPQ2d 1673 (Fed. Cir. 2000).

In the instant case, instant application 10/721693 does not point to any particular passages or sections in 09/864,646, or make any references to material therein relating to the use of radiographic markers in catheters or intracranial access devices, and there is no description in the instant application of any catheter or intracranial access device comprising a radiographic marker. Thus, there is no support for the amendment importing the term "radiographic marker" into the claims.

With regard to #3, above, adequate written description does not exist in the instant application for an siRNA that hybridizes to SEQ ID NO:1. At page 30, the specification discloses an siRNA comprising SEQ ID NO:1 and 2, said to be targeted to positions 945 through 965 in the ataxin1 gene corresponding to SEQ ID NO:15. Comparison t SEQ ID NO:15 shows that SEQ ID NO:1 represents the sense strand; SEQ ID NO:2, the antisense strand. While the sequence corresponding to positions 945 through 965 is identical to SEQ ID NO:1, SEQ ID

NO:2 does not hybridize to the full sequence, and applicant has not described an siRNA that hybridizes to the 21-nucleotide sequence SEQ ID NO:1 specifically. The siRNA described, comprising SEQ ID NO:1 and 2 does not hybridize to all 21-nucleotides of SEQ ID NO:1, as required by claim 1.

With regard to #4, above, adequate written description support does not exist in the instant application for the genus of siRNAs comprising SEQ ID NO:2 and a sequence at least 90% complementary thereto. While the specification teaches generally at page 14 that an siRNA may be 90% complementary to a target and still have activity, for example 19 out of 21 bases may be base paired, this disclosure addresses the interaction between an antisense strand in any given siRNA, such as that comprising SEQ ID NO:2 disclosed at page 30, and the target sequence. This disclosure does not address the structure of the 15-30 nucleotide sense strand component of the siRNA, and which 10% of the bases therein may be less than fully complementary to the antisense strand in an siRNA while maintaining activity.

Accordingly, while adequate written description exists for the siRNA comprising SEQ ID NO:1 and 2, adequate written description does not exist for the plurality of species thereof, as now claimed.

Claims dependent on claims 1 and 90 are rejected therefor.

Accordingly, the instant claims as a whole are rejected for lack of written description support.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/
Examiner, Art Unit 1635
March 9, 2009